

IN RE: DIET DRUGS (PHENTERMINE/
FENFLURAMINE/DEXFENFLURAMINE)
PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO:

SHEILA BROWN, et al.

v.

AMERICAN HOME PRODUCTS
CORPORATION

CIVIL ACTION NO. 99-20593

2:16 MD 1203

Bartle, C.J.

January 29, 2010

Melinda Fugitt ("Ms. Fugitt" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").²

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is to be completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In May 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Winston H. Gandy, Jr., M.D. Based on an echocardiogram dated April 7, 2002, Dr. Gandy attested in Part II of Ms. Fugitt's Green Form that she suffered from moderate mitral regurgitation,³ and an ejection

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serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

3. Dr. Gandy also attested that Ms. Fugitt suffered from moderate aortic regurgitation. As Ms. Fugitt's claim does not present any of the complicating factors necessary to receive Matrix Benefits for damage to her aortic valve, her level of aortic regurgitation is not relevant to this claim. See Settlement Agreement § IV.B.2.c.(2)(a).

fraction in the range of 50% to 60%.⁴ Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$524,135.⁵

In the report of claimant's echocardiogram, Dr. Gandy indicated that claimant had moderate mitral regurgitation with an RJA/LAA ratio of 25%. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. Dr. Gandy also stated that claimant's ejection fraction was 60%. An ejection fraction is considered reduced for purposes of a mitral valve claim if it is measured as less than or equal to 60%. See id.

§ IV.B.2.c.(2)(b)iv).

In October 2002, the Trust notified Ms. Fugitt that her claim had been selected for audit.⁶ Despite an opportunity to do

4. Dr. Gandy also attested that claimant had New York Heart Association Functional Class I symptoms. This condition, however, is not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). A reduced ejection fraction is one of the complicating factors needed to qualify for a Level II claim. See id. § IV.B.2.c(2)(b)iv).

6. Under the Settlement Agreement, Wyeth and the Trust each designated for audit a certain number of claims for Matrix Benefits and identified the condition(s) to be reviewed during the audit. See Settlement Agreement §§ VI.E. and VI.F.; Pretrial (continued...)

so, claimant did not submit additional medical information in support of her claim. In November 2002, the Trust forwarded the claim for review by Waleed N. Irani, M.D., one of its auditing cardiologists. In audit, Dr. Irani concluded that there was no reasonable medical basis for Dr. Gandy's finding that claimant had moderate mitral regurgitation because she had "[m]ild mitral regurgitation with underestimated [left atrium]" and there was "incomplete apical imaging with poor window used to trace [left atrial] area." Dr. Irani also concluded that there was no reasonable medical basis for Dr. Gandy's finding of a reduced ejection fraction, noting that claimant's ejection fraction was 65%.⁷

Based on the auditing cardiologist's diagnoses of mild mitral regurgitation and an ejection fraction greater than 60%, the Trust issued a post-audit determination denying Ms. Fugitt's claim. Pursuant to the Audit Policies and Procedures, claimant contested this adverse determination and requested that the claim proceed to the show cause process established in the Settlement

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Order ("PTO") No. 2457 (May 31, 2002), Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit ("Audit Policies and Procedures") § III.B. Here, the auditing cardiologist was asked to review claimant's level of mitral regurgitation and ejection fraction. In PTO No. 2662 (Nov. 26, 2002), we ordered the Trust to audit every claim submitted for Matrix Benefits. The present claim was designated for audit prior to the court's issuance of PTO No. 2662.

7. Dr. Irani also concluded that claimant had mild, as opposed to moderate, aortic regurgitation. As stated above, however, this condition is not at issue in these proceedings.

Agreement. See Settlement Agreement § VI.E.7; PTO No. 2457, Audit Policies and Procedures § IV.C.⁸ The Trust then applied to the court for issuance of an Order to show cause why Ms. Fugitt's claim should be paid. On March 10, 2003, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 2777 (Mar. 10, 2003).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on June 9, 2003. Under the Audit Policies and Procedures it is within the Special Master's discretion to appoint a Technical Advisor⁹ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Policies and Procedures § VI.J. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust

8. Claims placed into audit on or before December 1, 2002 are governed by the Audit Policies and Procedures, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Rules for the Audit of Matrix Compensation Claims, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Policies and Procedures contained in PTO No. 2457 apply to Ms. Fugitt's claim.

9. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. § VI.O.

The issues presented for resolution of this claim are whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's findings that she had moderate mitral regurgitation and a reduced ejection fraction. See id. § VI.D. Ultimately, if we determine that there is no reasonable medical basis for the answers in claimant's Green Form that are at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. VI.Q. If, on the other hand, we determine that there is a reasonable medical basis for the answers, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id.

In support of her claim, Ms. Fugitt submitted the Affidavit of Paul Moulinie, M.D., F.A.C.C. In his affidavit, Dr. Moulinie stated that claimant had moderate mitral regurgitation with an RJA/LAA ratio between 20% and 40% and an ejection fraction in the range of 50% to 60%. Claimant also argues that the auditing cardiologist failed to calculate her RJA/LAA ratio and, as a result, "there is no way to determine if Dr. Gandy's interpretation of the RJA/LAA is not medically reasonable."¹⁰

10. Claimant also provided a letter from Dr. Gandy, which
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In response, the Trust argues that claimant failed to present any evidence to dispute Dr. Irani's findings. The Trust also argues that Dr. Irani properly applied the standards set forth in the Settlement Agreement.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's findings of moderate mitral regurgitation and a reduced ejection fraction. Specifically, Dr. Vigilante determined that claimant had only mild mitral regurgitation, and her RJA/LAA ratio "was less than 10% in all measured cardiac cycles." As Dr. Vigilante explained:

[o]nly mild mitral regurgitation was noted in the parasternal long axis view with a very narrow jet. This was noted in real-time. The RJA/LAA was less than 10%. The supposed mitral regurgitant jet area traced on the tape was a non-representative frame. This mostly was "backflow" noted at the instance of the beginning of systole. It is clear on real-time evaluation that the mitral regurgitation is quite mild. Only trace mitral regurgitation was noted in a couple of the cardiac cycles in the apical four-chamber view.

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purportedly confirms his prior findings and explains that images on the echocardiogram created a false impression of an increased ejection fraction. This letter, however, references another claimant's name and states that the claimant's RJA/LAA ratio is 35% and that a photograph of the mitral regurgitation is attached. Although there is a line drawn through the referenced claimant's name and Ms. Fugitt's name is handwritten on the letter, Dr. Gandy originally opined that claimant's RJA/LAA ratio was only 25%. Additionally, the referenced photograph is not attached.

Dr. Vigilante also determined that claimant's ejection fraction was 65%. Specifically, Dr. Vigilante noted:

[t]he left ventricular ejection fraction was noted to be 65% using the parasternal windows. There were not enough cardiac cycles in the apical view to calculate the ejection fraction from those images. The right-sided cardiac structures were normal. It should be noted that the left ventricular internal dimensions were normal in both end systole (2.9 cm) and in end diastole (4.6 cm).

After reviewing the entire Show Cause Record before us, we find claimant's arguments are without merit. First, and of crucial importance, claimant does not contest the deficiencies noted by both the auditing cardiologist and Technical Advisor.¹¹ Specifically, the auditing cardiologist concluded that Ms. Fugitt's LAA was underestimated, the apical imaging on her echocardiogram was incomplete, and a "poor window" was used to trace her LAA. The Technical Advisor determined that the mitral regurgitant jet traced on claimant's echocardiogram was a non-representative frame and "mostly was 'backflow' noted at the instance of the beginning of systole." With respect to claimant's ejection fraction, the Technical Advisor further determined that claimant's ejection fraction in the parasternal view was 65%, and that the echocardiogram did not include "enough cardiac cycles in the apical view to calculate the ejection fraction"

11. Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Policies and Procedures § VI.N.

Finally, we disagree with claimant's arguments concerning the required method for evaluating a claimant's level of valvular regurgitation. Moderate mitral regurgitation is defined as an RJA/LAA ratio in the range of 20% to 40%, which is based on the grading system required by the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). Although the Settlement Agreement specifies the percentage of regurgitation needed to qualify as having moderate mitral regurgitation, it does not specify that actual measurements must be made on an echocardiogram to determine the amount of a claimant's regurgitation. As we explained in PTO No. 2640, "'[e]yeballing' the regurgitant jet to assess severity is well accepted in the world of cardiology." See PTO No. 2640 at 15 (Nov. 14, 2002).

Claimant essentially requests that we write into the Settlement Agreement a requirement that actual measurements of mitral regurgitation be made to determine if a claimant qualifies for Matrix Benefits. There is no basis for such a revision and claimant's argument is contrary to the "eyeballing" standards we previously have evaluated and accepted.¹²

For the foregoing reasons, we conclude that claimant has not met her burden in proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation and a reduced ejection fraction. Therefore, we

12. Claimant's argument as to the calculation of her RJA/LAA ratio also is flawed because, although not necessary, the Technical Advisor quantified her RJA/LAA ratio as less than 10%.

will affirm the Trust's denial of Ms. Fugitt's claim for Matrix Benefits.